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09

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/424,080 02/14/00 ZAVIALOV

V 933-149PCT

EXAMINER
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HM12/1012

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JAMROZ, M	
ART UNIT	PAPER NUMBER

1644  
DATE MAILED:

10/12/01

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/424,080

Applicant(s)

ZAVIALOV ET AL.

Examiner

Margaret E Jamroz

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1 and 3-18 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *restriction election facsimile*

Art Unit: 1644

### DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating papers for this application, all further correspondence regarding this application should be directed to Megan Jamroz in Art Unit 1644, Technology center 1600.

2. Applicant's amendment, filed on August 13, 2001 (Paper No. 13), is acknowledged.

Claims 1, 3, and 4 have been amended.

Claim 2 has been canceled.

Claims 5-18 have been added.

Claims 1 and 3-18 are pending in the instant application.

Examiner acknowledges election (Paper No. 13) filed on August 13, 2001.

Upon re-consideration, the following unity of invention has been set forth.

Upon re-consideration, including applicant's arguments, filed August 13, 2001 (Paper No. 13); the previous species election with respect to the immunosuppressants (cyclosporins, FK506, and rapamycin) has been withdrawn.

While the bioactive peptides have structural homology, a-peptiferin, albeferon and albebetin are distinct molecules, and their immunomodulatory activity is complex, as acknowledged on page 4, paragraph 2 of the instant specification. Therefore, the species election with respect to the bioactive peptides is maintained.

### *Sequence Compliance*

3. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

### *Election/Restrictions*

4. This application contains the following inventions, or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

5. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1 and 3-11, drawn to a composition comprising an immunosuppressant and a bioactive peptide to inhibit T cell proliferation.

Art Unit: 1644

Group II, claims 12-18, drawn to a method of amplifying the activity of the immunosuppressant with a composition comprising an immunosuppressant and a bioactive peptide to inhibit T cell proliferation.

6. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions of Group I was found to have no special technical feature that defined the contribution over the prior art of de Boer et al. (US Pat. No. 5,747,034; see entire document).

De Boer et al. teach and claim a method for treating transplant rejection in a patient with a therapeutically effective amount of (a) an antibody or an antigen binding fragment thereof (bioactive peptide) and (b) an immunosuppressive agent in a pharmaceutically acceptable excipient, wherein the immunosuppressive agent is selected from the group consisting of cyclosporin A, FK506, rapamycin and corticosteroids. De Boer et al. also teach a composition for inducing T cell anergy comprising in combination a monoclonal antibody or antigen binding fragment thereof (bioactive peptide) and an immunosuppressive agent; wherein the immunosuppressive agent is a member selected from the group consisting of cyclosporin A, FK506, rapamycin, and corticosteroids. (See entire document, and especially the background of the invention and the claims.)

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

7. This application contains claims directed to the following patentably distinct species of the claimed Inventions I-II: wherein the bioactive peptide is:

- A) a-peptoferin,
- B) albeferon,
- C) albebetin, or
- D) mixtures thereof.

In addition, to the species election above, application contains claims directed to the following patentably distinct species of the claimed Inventions I-II, wherein the bioactive peptide comprises one of the following sequences

- A) SEQ ID NO: 1, or
- B) SEQ ID NO: 2.

These species are distinct because the structure of the sequences are different, and thus represent patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 12 are generic.

Applicant is invited to clarify the relationship between the bioactive peptides set forth in claim 11 and SEQ ID NOS: 1 and 2.

8. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Jamroz, whose telephone number is (703) 308-8365. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Application/Control Number: 09/424,080

Page 5

Art Unit: 1644

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Margaret (Megan), Ph.D.  
Patent Examiner  
Technology Center 1600  
October 11, 2001

Phillip Gambel  
PHILLIP GAMBEL, PH.D  
PRIMARY EXAMINER  
Tech Center 1600  
10/11/01